STATE OF MICHIGAN

COURT OF APPEALS

ATTORNEY GENERAL, STATE OF MICHIGAN, and DEPARTMENT OF COMMUNITY HEALTH,	FOR PUBLICATION March 17, 2011
Plaintiffs-Appellees,	
v	No. 292003 Ingham Circuit Court
MERCK SHARP & DOHME CORPORATION, f/k/a MERCK & COMPANY, INC.,	LC No. 08-001132-CZ
Defendant-Appellant.	Advance Sheets Version

Before: SAWYER, P.J., and FITZGERALD and SAAD, JJ.

FITZGERALD, J. (*dissenting*).

I respectfully dissent. In my view, the trial court properly determined that plaintiffs' claim under the Medicaid False Claim Act (MFCA), MCL 400.601 *et seq.*, as pleaded, is not a products-liability action subject to the absolute defense established by MCL 600.2946(5). Consequently, the trial court properly declined to grant summary disposition in favor of defendant, Merck Sharpe & Dohme Corporation.

Defendant's motion for summary disposition was brought pursuant to MCR 2.116(C)(8). A motion under MCR 2.116(C)(8) tests the legal sufficiency of the complaint and is limited to the pleadings alone. All well-pleaded factual allegations are accepted as true and construed in a light most favorable to the nonmovant. *Maiden v Rozwood*, 461 Mich 109, 119-120; 597 NW2d 817 (1999). A motion under MCR 2.116(C)(8) may be granted only when the claims alleged are "'so clearly unenforceable as a matter of law that no factual development could possibly justify recovery.'" *Id*. at 119 (citation omitted). When deciding a motion brought under this subrule, a court considers only the pleadings. MCR 2.116(G)(5); *Maiden*, 461 Mich at 119-120.

Defendant is the manufacturer of the prescription pain reliever Vioxx, which was approved by the Food and Drug Administration (FDA) in May 1999 for the treatment of osteoarthritis, the management of acute pain in adults, and the treatment of primary dysmenorrhea. Subsequent clinical trials and independent studies conducted *after* Vioxx was approved by the FDA showed that patients using Vioxx had four or five times as many heart attacks as patients using the over-the-counter pain reliever Aleve. In 2004, defendant voluntarily removed Vioxx from the market.

On August 21, 2008, plaintiffs brought this action under the MFCA.[1] The gist of plaintiffs' complaint is that defendant fraudulently induced the state of Michigan to cover Vioxx under Medicaid by failing to adequately disclose its risks.[2] Plaintiffs alleged that defendant learned through clinical trials as early as 2000 that Vioxx posed a risk of heart attacks and other adverse cardiovascular events and that defendant did not disclose this knowledge to the public. They also alleged that defendant used a marketing campaign to maximize the sale of Vioxx and, in the course of doing so, attempted to minimize the safety risks of Vioxx and overstate its efficacy. Plaintiffs averred that if defendant had been truthful about the safety and efficacy of Vioxx, the state would not have paid all or part of the $20 million cost of Vioxx prescribed to Michigan Medicaid beneficiaries.

Defendant moved for summary disposition and asserted that plaintiffs' MFCA claim was, in truth, a products-liability claim that attempted to avoid the absolute defense of MCL 600.2946(5).[3] MCL 600.2946(5) immunizes manufacturers and sellers of an FDA-approved drug from liability in a products-liability action if the drug complied with FDA standards and labeling when it left the manufacturer's or seller's control.[4] *Taylor v Gate Pharm*, 468 Mich 1, 6-7; 658 NW2d 127 (2003). The trial court denied the motion. The court concluded that plaintiffs' claim did not constitute a products-liability action because it did not require proof of a defective or unsafe product. The trial court also concluded that the Legislature did not intend for MCL 600.2946(5) to foreclose actions under the MFCA.

---

[1] Plaintiffs relied on § 7 of the MFCA, which provides, in pertinent part:

> (1) A person shall not make or present or cause to be made or presented to an employee or officer of this state a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, upon or against the state, knowing the claim to be false.
>
> (2) A person shall not make or present or cause to be made or presented a claim under the social welfare act, 1939 PA 280, MCL 400.1 to 400.119b, that he or she knows falsely represents that the goods or services for which the claim is made were medically necessary in accordance with professionally accepted standards. [MCL 400.607(1) and (2).]

[2] Plaintiffs' complaint also included a claim of unjust enrichment.

[3] Defendant relied on *Duronio v Merck & Co, Inc*, unpublished opinion per curiam of the Court of Appeals, issued June 13, 2006 (Docket No. 267003), in which a panel of this Court affirmed a trial court's grant of summary disposition in favor of defendant in a similar case. In *Duronio*, the plaintiff asserted a fraud claim and a violation of the Michigan Consumer Protection Act, MCL 445.901 *et seq*., on the basis of allegations that the defendant misrepresented or concealed the risks associated with Vioxx.

[4] An exception to the absolute defense exists in situation involving fraud or bribery in dealings with the FDA. See MCL 600.2946(5)(a) and (b).

Defendant argues on appeal that, despite plaintiffs' labeling of its cause of action as a claim under the MFCA, plaintiffs' claim is a products-liability action as defined in MCL 600.2945(h) and used in MCL 600.2946(5).[5]

MCL 600.2946(5) states, in pertinent part:

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer or seller is not liable, if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

In interpreting this provision, our Supreme Court has stated, "[T]he Legislature has determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie." *Taylor*, 468 Mich at 7. In other words, a drug that has obtained FDA approval is "not defective or unreasonably dangerous" for purposes of a products-liability action.

MCL 600.2945 defines "product liability action" and "production" as follows:

> (h) "Product liability action" means an action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person or damage to property caused by or resulting from the production of a product.
>
> (i) "Production" means manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling.

Thus, plaintiffs' claim is a "product liability action" subject to the absolute defense of MCL 600.2946(5) if (1) the action is based on a legal or equitable theory of liability, (2) the action is brought for the death of a person or for an injury to a person or damage to property, and (3) that loss was caused by or resulted from the manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling of a product.

---

[5] Notably, defendant has not asked this court to resolve the question whether defendant's actions concerning its introduction and continued sale of Vioxx could be deemed sufficient to state a cause of action for a violation of the MFCA.

The point of contention is whether plaintiffs' claim was "brought for the death of a person or for injury to a person or damage to property . . . ." Plaintiffs are seeking money damages "representing Medicaid overpayments wrongfully received by Defendant" as a result of defendant's allegedly fraudulent conduct that occurred *after* the FDA's approval of Vioxx. To treat this case as a products-liability action would require a finding that plaintiffs' claim for money wrongfully paid was brought for *damage to property*.

In order to determine whether plaintiffs' claim was brought for "damage to property" pursuant to MCL 600.2945(h), this Court must interpret this phrase. "The fair and natural import of the provision governs, *considering the subject matter of the entire statute*." *People v McGraw*, 484 Mich 120, 124; 771 NW2d 655 (2009) (emphasis added). When examined in the proper context of a products-liability statute, it is clear that "damage to property" means *physical* damage to property caused by a defective or unreasonably dangerous product.

"Products liability is the name currently given to the area of the law involving the *liability* of those who supply goods or products for the use of others to *purchasers, users, and bystanders* for losses of various kinds *resulting from so-called defects in those products*." Prosser & Keeton, Torts (5th ed), § 95, p 677 (emphasis added). Indeed, the language in MCL 600.2946(5) refers to a products-liability action and defines when a drug is not "defective or unreasonably dangerous" for purposes of that action. Products liability includes multiple theories of recovery and types of losses. Prosser & Keeton, p 678, lists five different categories of losses:

> (1) personal injuries, (2) physical harm to tangible things, other than the assembled product such as an automobile, a helicopter, or an industrial machine of some kind, (3) physical harm to or destruction of the assembled product purchased by the first purchaser for use, (4) physical harm to or destruction of a product that was constructed with or repaired with the use of the target seller's component part, and (5) direct economic loss resulting from the purchase of the inferior product, and indirect consequential loss, such as loss of profits, resulting from the unfitness of the product adequately to serve the purchaser's purposes, such as when a plastic pipe purchased for an irrigation system on a golf course is unsatisfactory and requires replacement.

The first four types of losses are based on personal injuries or physical damage to property. The fifth type is based on purely economic loss. Under Michigan jurisprudence, disputes involving economic loss relating to a transaction in goods are generally subject to article 2 of the Uniform Commercial Code, MCL 440.1101 *et seq.*, rather than the Revised Judicature act (RJA). See *Neibarger v Universal Cooperatives, Inc*, 439 Mich 512; 486 NW2d 612 (1992). The Court in *Neibarger* explained the rationale:

> The economic loss doctrine, simply stated, provides that "'[w]here a purchaser's expectations in a sale are frustrated because the product he bought is not working properly, his remedy is said to be in contract alone, for he has suffered only "economic" losses.'" This doctrine hinges on a distinction drawn between transactions involving the sale of goods for commercial purposes where economic expectations are protected by commercial and contract law, and those

> involving the sale of defective products to individual consumers who are injured in a manner which has traditionally been remedied by resort to the law of torts. [*Id*. at 520-521 (citations omitted).]

Thus, in the context of the RJA, losses based on personal injury or physical damage to property are the only actionable losses addressed under the rubric of products liability. Again, this is consistent with damages for harm caused by a defective or unsafe product.

If damage to property is given a broad interpretation, like that in *Duronio*, the statute would provide a manufacturer or seller of drugs immunity to claims for losses that are different from the four types of losses listed above and not contemplated by the Legislature. The definition of products-liability action must be considered in the context of a suit by purchasers, users, or bystanders who suffer losses resulting from defects in a product. Prosser & Keeton, p 677. The damages in this case do not derive from injuries to a purchaser, user, or bystander.[6] Our Supreme Court has explained that products liability "derive[d] either from a duty imposed by law or from policy considerations which allocate the risk of dangerous and unsafe products to the manufacturer and seller rather than the *consumer*." *Neibarger*, 439 Mich at 523 (emphasis added). Here, every section of the statute is written in the context of a suit by a purchaser, user, or bystander. Indeed, the definitions of "misuse" and "sophisticated user" in the MFCA make it clear that the potential plaintiff in a products-liability action is the user of the product. See MCL 600.2945(e) and (j).

On the basis of the foregoing, "damage to property" is properly interpreted as *physical damage* to property resulting from a defective or unreasonably dangerous product. As such, the present case is not a products-liability action, as defined in MCL 600.2945(h), because a suit brought for the return of Medicaid overpayments is not "brought for . . . damage to property . . . ." Accordingly, I would conclude that the trial court properly denied defendant's motion for summary disposition.

/s/ E. Thomas Fitzgerald

---

[6] The damages arise from an injury to Michigan's Medicaid program and represent the amount of money allegedly wrongfully paid to defendant.